Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1, 3, 5 and 12 are amended, claims 2 and 7 are canceled, and claim 36 is added. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the present application. Claims 1, 3-6, 8-14 and 16-36 are now pending in this application.

The 35. U.S.C. § 112, First Paragraph, Rejections

The Examiner rejected claim 1 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection, as it maybe maintained with respect to the pending claims, is respectfully traversed.

The Examiner is requested to consider that in Amgen v. Hoechst (65 U.S.P.Q.2d 1385 (Fed. Cir. 2003)), certain claims at issue were directed to types of cells that could be used to produce recombinant human erythropoietin. The Federal Circuit stated that the words "vertebrate" and "mammalian" readily "convey [] distinguishing information concerning [their] identity" such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus" and affirmed the district court's conclusion that disclosure of two species of vertebrate or mammalian cells was sufficient written description to support a "product" claim (page 1398).

The specification describes the use of two lectins known to bind to sialic acid containing molecules to select for cells, e.g., mammalian cells and avian cells, with reduced numbers of those molecules from parent cells known to be competent for influenza virus replication, e.g., bovine cells, swine cells, ferret cells, human cells, canine cells and avian cells, i.e., cells from organisms recognized as being susceptible to influenza virus infection (see Table 4 in Chapter 51 of Fields Virology, Knipe et al., eds., (1985), of record). Further, influenza virus is known to

bind to sialyl oligosaccharides on cells (page 1, lines 17-21 of the present specification), i.e., cells susceptible to influenza virus infection have sialyl oligosaccharides.

Accordingly, Applicant has conveyed relevant, identifying characteristics of the genus of claimed mammalian or avian mutant cells, e.g., by disclosing a functional characteristic coupled with a known or disclosed correlation between function and structure, e.g., lectins which bind terminal sialic acid containing residues are useful to select for cells with reduced terminal sialic acid containing receptors for influenza virus, such that one skilled in the art could visualize or recognize the identity of the members of the genus.

The Examiner also rejected claims 1-11 and 32-35 under 35 U.S.C. § 112, first paragraph, as containing new matter due to the recitation of "sialic acid containing molecules. The amendment to claim 1 to recite "terminal sialic acid containing host cell receptors" renders this rejection moot.

Hence, withdrawal of the rejections under § 112(1) is appropriate and respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejections

Claims 1-11 and 32-35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Specifically, the Examiner asserts that the first recitation of "sialic acid" in claim 1 is not preceded by the word "terminal" and that claims 34 and 35 are broader than claim 1, thereby rendering those claims indefinite.

The amendment to claim 1 to insert the word "terminal" before the first instance of "sialic acid" obviates the § 112(2) rejection of claim 1.

With respect to claims 34 and 35, it is Applicant's position that those claims, which clarify the specificity of the lectin for certain terminal sialic acid containing residues is clear and definite, further limit the scope of claim 1 which does not specify particular terminal sialic acid containing residues that are bound by the lectin.

Accordingly, withdrawal of the § 112(2) rejections is respectfully requested.

The 35 U.S.C. § 102(b) Rejections

Claims 1-4, 8, 32, and 34-35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Martin et al. (Virology, 241:101 (1998)) or Brandli et al. (J. Biol. Chem., 263:16283 (1988)), as evidenced by Doyle et al. (U.S. published application 2004/0132164) and Ito et al. (J. Virol., 71:3357 (1997)). Claims 1, 8, 32, and 34-35 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Matta et al. (Parasitol Res., 85:293 (1999)). These rejections, as they may be maintained with respect to the pending claims, are respectfully traversed.

Martin et al. disclose that influenza virus HA proteins with substitutions in the receptor binding site can affect the ability of HA to bind to human erythrocytes, presumably due to the reduced affinity of mutant HA for sialic acid (pages 105-106). It is disclosed that four transfectant viruses with mutant HAs were able to infect MDCK cells and embryonated chicken eggs with efficiencies comparable to wild-type (page 106), although the infectivity of one of the transfectant viruses on a mutant ricin-resistant MDCK cell ("MDCK RCA^r") was greatly reduced compared to wild-type MDCK cells. It is further disclosed that MDCK RCA^r cells have a 70 to 75% reduction in cell surface sialic acid (citing to Brandli et al., 1988), and that these cells may produce reduced virus yields (citing Green et al., J. Cell. Biol., 89:230 (1981)).

Brandli et al. disclose that a ricin-resistant MDCK cell line (MDCKII-RCA^r) and wild-type cells bind wheat germ agglutinin (specific for *N*-acetylglucosamine and *N*-acetylneuraminic acid), conconavalin A (specific for mannose) and *H. pomatia* agglutinin (*N*-acetylgalactosamine), which binding was unaffected by exogalactosylation (page 16286). It is further disclosed that wild-type cells did not contain significant amounts of *N*-acetylglucosamine (assessed by *B. simplicifolia* agglutinin binding) while mutant cells bound *B. simplicifolia* agglutinin, which could be eliminated by exogalactosylation. In contrast to wild-type cells, it is disclosed that mutant cells did not bind peanut lectin (specific for terminal galactose linked to *N*-acetylgalactosamine). While mutant cells had decreased binding to (70 to 75%) *Limax flavus* agglutinin (LFA, a lectin which binds sialyl residues in a non-glycosidic linkage specific manner, see Cross et al., J. Biol. Chem., 278:4112 (2003), of record) (pages 16287-8 of Brandli et al.), Brandli et al. conclude that MDCKII-RCA^r cells are deficient in the addition of galactose residues to *N*- and *O*-linked glycans (page 16286).

Ito et al. incubated frozen sections of avian allantoic cells, avian amniotic cells, and MDCK cells with digoxigenin labeled *Maakia amurensis* (MAA) lectin or *Sambucus nigra* (SNA) lectin to characterize the lectin binding specificity of those cells. Those cells were not grown in the presence of lectin, e.g., to select for cells that were to resistant to lectin growth inhibition.

Doyle et al. describe compositions and methods for enzymatic reduction of adhesion by microorganisms to cells, tissues, extracellular matrix teeth and/or dental prosthesis. Doyle et al. mention that polyphenol oxidase and the asparaginase are effective in reducing influenza A virus attachment to sialic acid containing red blood cells [see paragraph 320].

Matta et al. used labeled MAA and SNA to determine cell surface sialoglycoconjugate structures on wild-type and a formycin A resistant mutant of *Crithidia fasciculate*, a trypanosome. The mutant was obtained by treatment of wild-type *Crithidia fasciculate* with *N*-methyl-*N'*-nitro-*N*-nitrosoguanidine and selection for resistance to formycin A, an antibiotic (page 294).

Nevertheless, none of the cited references discloses a mutant mammalian or avian cell with reduced levels of *N*-acetylneuraminic acid or *N*-glycolylneuraminic acid.

Therefore, withdrawal of the § 102(b) rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date June 8, 2005

By _____
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of June, 2005.

Dawn M. Pole

Name

Dawn M. Pole

Signature